IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Campbell Rogers, Elazer R. Edelman, and Daniel I. Simon

Serial No.: 09/776,533 Group Art Unit: 1644

Filed: February 7, 2001 Examiner: Phillip Gambel

For: *MODULATION OF VASCULAR HEALING BY INHIBITION OF LEUKOCYTE ADHESION AND FUNCTION*

Box DAC
Assistant Commissioner for Patents
Washington, D.C. 20231

PETITION FOR RECONSIDERATION OF PETITION DECISION BY THE COMMISSIONER

Sir:

Pursuant to 37 C.F.R. § 1.144, applicants petition the Commissioner to review the restriction requirement set forth in the Office Action mailed June 11, 2002, made final in the Office Action mailed September 6, 2002 and the decision of the petition rendered December 18, 2002. No fee is believed to be due.

Remarks

The Office Action mailed June 11, 2002, divided the claims into 24 groups. These are appended for the convenience of the Commissioner in Appendix A. This application is a continuing application of 08/823,999 filed March 5, 1997, to which this application claims priority. In prosecution of the parent application, a restriction

requirement was imposed by the *same examiner* (See Appendix B), where the *same claims* were divided into only two groups, and an election of species was made. This application was not only prosecuted on this basis, but is currently on appeal at this time, with data and arguments submitted during prosecution and on appeal that were based on the original restriction requirement. These arguments are prejudicial to any prosecution by applicants that would have to be made in the present application based on the current restriction requirement.

It is respectfully requested that the Commissioner review the imposed restriction requirement and make the same restriction requirement as the parent, based on the same claims as now pending in this case.

CLAIMS 1-12 ARE PENDING

In the response filed July 11, 2002, applicants elected for prosecution group I, claims 1-12, and elected with traverse the species of Mac-1-specific antibodies. Claims 13-17 were cancelled. A petition for review of the restriction requirement was filed on October 4, 2002. In the decision mailed December 18, 2002, the petition was DENIED. Applicants request reconsideration of this decision. The Supervisor's comments are addressed in a point-by-point manner below.

Claims must be both patentably distinct and independent in order to be subject to restriction requirement. Definitions are provided by CHISUM 4:12.03[1]: The Patent and Trademark Office defines "independent" as meaning "not dependent," which

in turn means "there is no disclosed relationship between the two or more subjects disclosed." Examples include species not usable together as disclosed or process and apparatus incapable of being used in practicing the process. The Office cites the extreme example of a shoe and a locomotive bearing. The Office defines "distinct" as meaning related or dependent but "capable of separate manufacture, use or sale as claimed" and "patentable over each other." Examples of dependent and distinct inventions include combination and subcombination, process and apparatus, process and product, and composition and process of use under appropriate circumstances.

1. The Claimed Methods are Related.

In an election of species, only the elected species is initially examined. Once this claim is determined to be allowable, the examiner must search the remaining species. The claimed methods are related because they all have (1) a common mechanism of action; (2) a common target; and (3) a common result, i.e., "decreasing or inhibiting integrin-mediated stenosis or restenosis or a blood vessel".

Further, the MPEP states that species, "while usually independent, may be related under the particular disclosure. Where inventions as disclosed and claimed are both (A) species under a claimed genus and (B) related, then the question of restriction must be determined by both the practice applicable to election of species and the practice applicable to other types of restrictions such as those covered in MPEP 806.05-

806.05(i)." (MPEP 806.04(b))

The relationship between species is disclosed. Compounds that inhibit leukocyte adherence by inhibiting integrins or integrin ligands as stated on page 7 line 26 to page 8 line 6. The claimed method is directed to *a method of inhibiting stenosis or restenosis by inhibiting integrin-mediated cell adhesion.* Clearly blocking different members of the integrin family or an integrin ligand is encompassed by the scope of this method. "Current Patent and Trademark Office policy precludes restriction, even in the case of multiple species, unless the two groups of claims are patentable over each other (*i.e.*, neither is obvious in the light of the other) (Chisum 4:12.03).

The similarity of the members of the 24 groups is further demonstrated by the fact that they only belong to two class/subclass combinations. In the restriction requirement of the parent application, the examiner stated that the integrins and their receptors constituted distinct species because their structures and modes of action are different. Mac-1, LFA-1, p150,95, and CD11d/CD18 are all integrins. The ligands for these integrins overlap.

The present specification describes a relationship of the integrins all being involved in leukocyte adhesion (page 7, lines 16-21), and where the integrin ligands show promiscuity by binding to multiple integrins (page 7, lines 21-25). The specifically different embodiments of the invention are defined in proper Markush groups. "Broadly, unity of invention exists where compounds included within a

Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility" *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

The integrins all share a common utility of binding extracellular matrix. They are also composed of two non-covalently associated transmembrane glycoprotein subunits α and β, both of which contribute to binding the matrix. This structural feature is essential to the utility. Unity of invention exists. Blocking any of the disclosed receptors or ligands will inhibit leukocyte adhesion to prevent stenosis/restenosis.

2. It would not create an undue burden on the Examiner to search one group of the method of claims 1-12, using the elected species, and then the remaining species.

The same examiner has already searched the group consisting of claims 1-12 with the same elected species in the parent application. It can hardly represent an additional burden to conduct the exact same search in the continuation application.

3. Claim 1 is a Generic Claim; Restriction is Legally Incorrect

The MPEP provides that if an applicant discloses multiple species but includes only generic claims, election between species is normally not required. If an applicant discloses multiple species and includes claims restricted to those species, the applicant will be required to elect one species. He will then be restricted to those claims that read on that elected species unless a generic claim is found to be allowable. In the latter

event, the applicant may include further claims to additional species (up to a reasonable number) provided that such additional claims "are written in dependent form (Rule 75), or otherwise include all the limitations of the generic claim."

This is exactly the situation here. Claim 1 is generic. In the restriction requirement of the parent application, the examiner stated that claim 1 and claim 13 (now cancelled) are proper generic claims. It is inconsistent for a generic claim previously satisfying the requirements of MPEP 806.04(d) to be deemed not generic at a later date.

The restriction requirement, by creating separate inventions out of the generic claim, makes it impossible to examine claim 1 in its entirety, and forces the applicants to restrict it to a single species.

The examiner has no legal authority to require applicants to restrict a generic claim to a single species, absent prior art or lack of enablement.

4. Equity Requires examination of Claims 1-12 as a single group

The parent case, based on the claims as originally restricted by this same examiner, has been examined by this same examiner, evidence submitted, and is now on appeal. It would unfairly prejudice the Applicants to make a restriction requirement of the same claims which have already been prosecuted and which are now waiting at the Board of Appeals. Arguments have been made arguing results with one species are predictive of results with another species, all of which are joined by a common function

(i.e. the inhibition of leukocyte adhesion and function). It is well established that a genus can be linked by a common function, to achieve a common result: in this case, modulation of vascular healing, and in particular, prevention or mitigation of restenosis.

In *Mark I Marketing Corp. v. R.R. Donnelley & Sons Co.* (1995), 154. the Federal Circuit stressed that `` 'The prosecution history must be examined as a whole in determining whether estoppel applies.' '': ``Thus, the relevant prosecution history here includes not only the ... application [upon which the patent issued] but also the parent ... and grandparent ... applications. Chisum 5A:18.05[2][d][ii]

The Examiner should be bound by the final decisions he rendered during the prosecution of claims 1-12 as a single invention in the parent application. These claims have been prosecuted together as a group under the same prior art references in office actions of the parent. The previous history of prosecuting this group of claims as one invention acknowledges that they are related. It is inconsistent to restrict the exact same claims differently in this application than in the parent application.

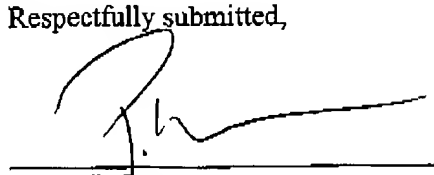
SUMMARY

The current restriction imposed on the claims of the present invention is improper. This restriction is inconsistent with the guidelines for restriction practice delineated by the MPEP. The claims of this invention are directed to the method for inhibiting stenosis or restenosis. Upholding this restriction requirement would be to allow the examiner to impose limitations on the claims ***which are not now present.***

U.S.S.N. 09/776,533
Filed: February 7, 2001
PETITION FOR SUPERVISORY REVIEW BY THE COMMISSIONER

Favorable consideration of this petition is earnestly solicited.

Respectfully submitted,



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APPENDIX A: *Clean Copy of Claims as Pending*

1. A method of inhibiting or reducing stenosis or restenosis of a blood vessel following injury to vascular tissue in a region of the blood vessel of a patient in need of treatment thereof, comprising:

administering systemically or at the site of the injury a pharmaceutically acceptable composition comprising a compound which specifically inhibits or reduces leukocyte integrin-mediated adhesion or function in an amount effective to inhibit or reduce stenosis or dependent restenosis of a blood vessel following injury to vascular tissue.

2. The method of claim 1 wherein the leukocytes are monocytes or granulocytes.

3. The method of claim 1 wherein the injury arises from angioplasty, atherectomy, endovascular stenting, coronary artery bypass surgery, peripheral bypass surgery, or transplantation of cells, tissue or organs.

4. The method of claim 1 wherein the composition is in a form selected from the group consisting of solutions, gels, foams, suspensions, polymeric carriers, and liposomes.

5. The method of claim 1 wherein the integrin is selected from the group consisting of Mac-1, LFA-1, p150,95, and CD11d/CD18.

6. The method of claim 5 wherein the integrin is Mac-1.

7. The method of claim 6 wherein the ligand is selected from the group consisting of ICAM-1, fibrin(ogen), C3bi, and factor X.

8. The method of claim 1 wherein the compound is selected from the group consisting of antibodies and antibody fragments that are immunoreactive with integrins or their ligands and which block the interaction of the integrins or their ligands with vascular cells; molecules which inhibit expression of the integrins or their ligands, and

peptides and peptidomimetics derived from the integrins or their ligands which block the interaction of the integrins or their ligands with vascular cells or tissues.

9. The method of claim 5 wherein the integrin is LFA-1 and the ligand is selected from the group consisting of ICAM-1, ICAM-2, ICAM-3.

10. The method of claim 6 wherein the compound is an antibody or antibody fragment immunoreactive with Mac-1.

11. The method of claim 1 wherein the compound is administered to a patient in need thereof prior to vascular intervention.

12. The method of claim 11 wherein the compound is administered to a the patient prior to and after vascular intervention, until healing has occurred.

Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

08/823,999

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/823,999	03/25/97	ROGERS	C MIT7501

EXAMINER	
GAMBEL P	

ART UNIT	PAPER NUMBER
1644	7

HM11/0728

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DATE MAILED: 07/28/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 30 DAYS month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 1-17 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☑ Claims 1-17 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

DOCKETED FOR (1) 8-27-98 Resp W/O EOT DUE
BY JSH (2) 9-28-98 Resp W/1 EOT DUE
DATE 8-4-98 (3) 10-28-98 Rsp W/2 EOT DUE
(4) 11-28-98 Rsp W/3 EOT DUE
(5) 12-28-98 Rsp W/4 EOT Due
(6) 1-28-99 Rsp W/5 EOT Due

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

RECEIVED
AUG 03 1998
PATENT DEPT.

– SEE OFFICE ACTION ON THE FOLLOWING PAGES –

* U.S. GPO: 1998-410-236/40080

Serial No. 08/823999
Art Unit 1644

DETAILED ACTION

1. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-12, drawn to methods of inhibiting stenosis or restenosis with integrin-specific antibodies, molecules and peptides, classified in Class 424, subclass 130.1 and Class 514, subclass 8

II. claims 13-17, drawn to compositions comprising integrin-specific antibodies, molecules and peptides, classified in Class 424, subclass 130.1 and Class 514, subclass 8.

3. Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as affinity purification or detection assays.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II and Groups I and II have acquired a separate status in the art as shown by their divergent subject matter, restriction for examination purposes as indicated is proper.

5. In addition to electing Group I or Group II, applicant is required to elect a species from each of (A) and (B) set forth herein.

A) This application contains claims directed to the following patentably distinct species of the claimed invention: wherein the integrin specificity is:

i) Mac-1,
ii) LFA-1,
iii) p150,95,
iv) CD11d/CD18
v) ICAM-1
vi) fibrinogen,
vii) C3bi or
viii) factor X

These species are distinct because their structures and modes of action are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 (Group I) and claim 13 (Group II) are generic.

B) This application contains claims directed to the following patentably distinct species of the claimed invention: wherein the compound/composition is:

I) an antibody,
ii) molecules which inhibits integrin or ligand expression
iii) integrin/ligand-derived peptides or peptidomimetics,

These species are distinct because their structures and modes of action are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 (Group I) and claim 13 (Group II) are generic.

Applicant is invited to clearly identify the species from both (A) and (B)

6. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Serial No. 08/823999
Art Unit 1644

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.
Patent Examiner
Technology Center 1600
Group 1640
July 27, 1998